

Please replace the paragraph beginning on page 15, line 1, with the following rewritten paragraph:

a1 -- FIG. 1 is a graph of testosterone concentrations ( $\square$ ), DHT concentrations ( $\bullet$ ), and the DHT/T ratio for patients receiving a subdermal testosterone pellet implant over a period of 300 days after implantation. --

Please replace the paragraph beginning on page 15, line 7, with the following rewritten paragraph:

AB 104544-04123  
-- FIG. 3 is a 24-hour testosterone pharmacokinetic profile for patients receiving the TESTODERM<sup>®</sup> TTS patch ( $\blacksquare$ ), as compared to baseline testosterone serum concentration levels ( $\bullet$ ). --

Please replace the paragraph beginning on page 15, line 11, with the following rewritten paragraph:

AB -- FIG. 5(a) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men prior to receiving 5.0 g/day of AndroGel<sup>®</sup> (- - -), 10.0 g/day of AndroGel<sup>®</sup> (— —), or the testosterone patch (—) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - —) line. --

Please replace the paragraph beginning on page 15, line 14, with the following rewritten paragraph:

a4 -- FIG. 5(b) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men on the first day of treatment with either 5.0 g/day of AndroGel<sup>®</sup> (- - -), 10.0

Q4  
CONT- g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group).

Normal high and low testosterone levels (ng/dl) are represented by the (— - - -) line. --

Please replace the paragraph beginning on page 15, line 17, with the following rewritten paragraph:

Q5  
-- FIG. 5(c) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men on day 30 of treatment with either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - -) line. --

10046454-04600  
Please replace the paragraph beginning on page 15, line 20, with the following rewritten paragraph:

Q6  
-- FIG. 5(d) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men on day 90 of treatment with either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - -) line. --

Please replace the paragraph beginning on page 16, line 1, with the following rewritten paragraph:

Q7  
-- FIG. 5(e) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men on day 180 of treatment with either 5.0 g/day of AndroGel® (- - - -), 7.5 g/day of AndroGel® (— - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by

Q7  
cont. final treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— — — —) line. --

Please replace the paragraph beginning on page 16, line 4, with the following rewritten paragraph:

Q8 -- FIG. 5(f) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men on day 0 (- - - -), 1 (— —), 30 (—), 90 (— - -), and 180 (—) of treatment with 5.0 g/day of AndroGel®. Normal high and low testosterone levels (ng/dl) are represented by the (— — — —) line. --

Q9  
2024-12-14 15:44:00  
Please replace the paragraph beginning on page 16, line 6, with the following rewritten paragraph:

-- FIG. 5(g) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men on day 0 (- - - -), 1 (— —), 30 (—), 90 (— - -), and 180 (—) of treatment with 10.0 g/day of AndroGel®. Normal high and low testosterone levels (ng/dl) are represented by the (— — — —) line. --

Please replace the paragraph beginning on page 16, line 8, with the following rewritten paragraph:

Q10 -- FIG. 5(h) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men on day 0 (- - - -), 1 (— —), 30 (—), 90 (— - -), and 180 (—) of treatment with the testosterone patch. Normal high and low testosterone levels (ng/dl) are represented by the (— — — —) line. --

Please replace the paragraph beginning on page 16, line 10, with the following rewritten paragraph:

Q11  
-- FIG. 6(a) is a graph showing the 24-hour free testosterone pharmacokinetic profile for hypogonadal men on day 1 of treatment with either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - - -) line. --

Please replace the paragraph beginning on page 16, line 13, with the following rewritten paragraph:

Q12  
2022-04-12 10:46:45  
-- FIG. 6(b) is a graph showing the 24-hour free testosterone pharmacokinetic profile for hypogonadal men on day 30 of treatment with either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - - -) line. --

Please replace the paragraph beginning on page 16, line 16, with the following rewritten paragraph:

Q13  
-- FIG. 6(c) is a graph showing the 24-hour free testosterone pharmacokinetic profile for hypogonadal men on day 90 of treatment with either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - - -) line. --

Please replace the paragraph beginning on page 16, line 19, with the following rewritten paragraph:

Q14 -- FIG. 6(d) is a graph showing the 24-hour free testosterone pharmacokinetic profile for hypogonadal men on day 180 of treatment with either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 16, line 22, with the following rewritten paragraph:

Q15 10046454-04-1202 -- FIG. 6(e) is a graph showing the 24-hour free testosterone pharmacokinetic profile for hypogonadal men on day 0 (- - - -), 1 (— —), 30 (——), 90 (— - -), and 180 (——) of treatment with 5.0 g/day of AndroGel®. Normal high and low testosterone levels (ng/dl) are represented by the (— - - - -) line. --

Please replace the paragraph beginning on page 17, line 1, with the following rewritten paragraph:

Q16 -- FIG. 6(f) is a graph showing the 24-hour free testosterone pharmacokinetic profile for hypogonadal men on day 0 (- - - -), 1 (— —), 30 (——), 90 (— - -), and 180 (——) of treatment with 10.0 g/day of AndroGel®. Normal high and low testosterone levels (ng/dl) are represented by the (— - - - -) line. --

Please replace the paragraph beginning on page 17, line 3, with the following rewritten paragraph:

Q17 -- FIG. 6(g) is a graph showing the 24-hour free testosterone pharmacokinetic profile for hypogonadal men on day 0 (- - - -), 1 (— —), 30 (—), 90 (— - -), and 180 (—) of treatment with the testosterone patch. Normal high and low testosterone levels (ng/dl) are represented by the (— - - -) line. --

Please replace the paragraph beginning on page 17, line 5, with the following rewritten paragraph:

Q18 -- FIG. 7 is a graph showing the DHT concentrations on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (—) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - -) line. --

Q19 Please replace the paragraph beginning on page 17, line 8, with the following rewritten paragraph:

-- FIG. 8 is a graph showing the DHT/T ratio on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (—) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - -) line. --

Please replace the paragraph beginning on page 17, line 11, with the following rewritten paragraph:

Q20 -- FIG. 9 is a graph showing the total androgen concentrations (DHT + T) on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of

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AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 17, line 14, with the following rewritten paragraph:

Q21  
-- FIG. 10 is a graph showing the E<sub>2</sub> concentrations on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

10046454-04202  
Please replace the paragraph beginning on page 17, line 17, with the following rewritten paragraph:

Q22  
-- FIG. 11 is a graph showing the SHBG concentrations on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 17, line 20, with the following rewritten paragraph:

Q23  
-- FIG. 12(a) is a graph showing the FSH concentrations on days 0 through 180 for men having primary hypogonadism and receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 18, line 1, with the following rewritten paragraph:

24 -- FIG. 12(b) is a graph showing the FSH concentrations on days 0 through 180 for men having secondary hypogonadism and receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

1004645441202  
2024-12-19 14:12:02  
Please replace the paragraph beginning on page 18, line 4, with the following rewritten paragraph:

25 -- FIG. 12(c) is a graph showing the FSH concentrations on days 0 through 180 for men having age-associated hypogonadism and receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 18, line 7, with the following rewritten paragraph:

26 -- FIG. 12(d) is a graph showing the FSH concentrations on days 0 through 180 for men having hypogonadism of an unknown origin and receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --



Please replace the paragraph beginning on page 18, line 10, with the following rewritten paragraph:

027 -- FIG. 13(a) is a graph showing the LH concentrations on days 0 through 180 for men having primary hypogonadism and receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 18, line 13, with the following rewritten paragraph:

028 -- FIG. 13(b) is a graph showing the LH concentrations on days 0 through 180 for men having secondary hypogonadism and receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

029 Please replace the paragraph beginning on page 18, line 16, with the following rewritten paragraph:

-- FIG. 13(c) is a graph showing the LH concentrations on days 0 through 180 for men having age-associated hypogonadism and receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 18, line 19, with the following rewritten paragraph:

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130 -- FIG. 13(d) is a graph showing the LH concentrations on days 0 through 180 for men having hypogonadism of an unknown origin and receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - -) line. --

Please replace the paragraph beginning on page 19, line 1, with the following rewritten paragraph:

131 -- FIG. 14(a) is a bar graph showing the change in hip BMD for hypogonadal men after 180 days of treatment with 5.0 g/day of AndroGel® (☒), 5.0 g/day of AndroGel® switched to 7.5 g/day of AndroGel® (wide hatch mark), 10.0 g/day of AndroGel® switched to 7.5 g/day of AndroGel® (narrow hatch marks), 10.0 g/day of AndroGel® (■), or the testosterone patch (□). --

132 Please replace the paragraph beginning on page 19, line 4, with the following rewritten paragraph:

132 -- FIG. 14(b) is a bar graph showing the change in spine BMD for hypogonadal men after 180 days of treatment with 5.0 g/day of AndroGel® (☒), 5.0 g/day of AndroGel® switched to 7.5 g/day of AndroGel® (wide hatch mark), 10.0 g/day of AndroGel® switched to 7.5 g/day of AndroGel® (narrow hatch marks), 10.0 g/day of AndroGel® (■), or the testosterone patch (□). --

Please replace the paragraph beginning on page 19, line 7, with the following rewritten paragraph:

133 -- FIG. 15 is a graph showing PTH concentrations on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (—

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B33  
cont  
—), or the testosterone patch (—) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - -) line. --

Please replace the paragraph beginning on page 19, line 10, with the following rewritten paragraph:

B34  
-- FIG. 16 is a graph showing SALP concentrations on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (—) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - -) line. --

10046454-00202  
Please replace the paragraph beginning on page 19, line 13, with the following rewritten paragraph:

B35  
-- FIG. 17 is a graph showing the osteocalcin concentrations on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (—) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - -) line. --

Please replace the paragraph beginning on page 19, line 16, with the following rewritten paragraph:

B36  
-- FIG. 18 is a graph showing the type I procollagen concentrations on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (—) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - -) line. --

Please replace the paragraph beginning on page 19, line 19, with the following rewritten paragraph:

037 -- FIG. 19 is a graph showing the N-telopeptide/Cr ratio on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 20, line 1, with the following rewritten paragraph:

10046541-04-1302 038 -- FIG. 20 is a graph showing the Ca/Cr ratio on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 21, line 7, with the following rewritten paragraph:

039 -- FIG. 24(a) is a bar graph showing the change in leg strength on days 90 and 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (diagonal hatch marks), 7.5 g/day of AndroGel® (horizontal hatch marks), 10.0 g/day of AndroGel® (⊠), or the testosterone patch (□). --

Please replace the paragraph beginning on page 21, line 10, with the following rewritten paragraph:

Q40 -- FIG. 24(b) is a bar graph showing the change in arm strength on days 90 and 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (diagonal hatch marks), 7.5 g/day of AndroGel® (horizontal hatch marks), 10.0 g/day of AndroGel® (☒), or the testosterone patch (□). --

Please replace the paragraph beginning on page 21, line 13, with the following rewritten paragraph:

Q41 10045154-041202 -- FIG. 25(a) is a bar graph showing the change in total body mass on days 90 and 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (diagonal hatch marks), 7.5 g/day of AndroGel® (horizontal hatch marks), 10.0 g/day of AndroGel® (☒), or the testosterone patch (□). --

Please replace the paragraph beginning on page 21, line 16, with the following rewritten paragraph:

Q42 -- FIG. 25(b) is a bar graph showing the change in lean body mass on days 90 and 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (diagonal hatch marks), 7.5 g/day of AndroGel® (horizontal hatch marks), 10.0 g/day of AndroGel® (☒), or the testosterone patch (□). --

Please replace the paragraph beginning on page 21, line 19, with the following rewritten paragraph:

-- FIG. 25(c) is a bar graph showing the change in fat mass on days 90 and 180 for

hypogonadal men receiving either 5.0 g/day of AndroGel® (diagonal hatch marks), 7.5 g/day of AndroGel® (horizontal hatch marks), 10.0 g/day of AndroGel® (☒), or the testosterone patch (□). --

Please replace the paragraph beginning on page 22, line 1, with the following rewritten paragraph:

-- FIG. 25(d) is a bar graph showing the change in percent body fat on days 90 and 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (diagonal hatch marks), 7.5 g/day of AndroGel® (horizontal hatch marks), 10.0 g/day of AndroGel® (☒), or the testosterone patch (□). --